

REMARKS/ARGUMENTS

Reconsideration of the present application, as amended, is respectfully requested.

Since the present amendment raises no new issues for consideration and, in any event, places the present application in better condition for consideration on appeal, it is respectfully requested that this amendment be entered under 37 CFR 1.116 in response to the last Office Action dated September 12, 2006, which made final rejections as to the pending claims.

A. STATUS OF THE CLAIMS

As a result of the present amendment, claims 1-3 and 5-15 remain in the case for continued prosecution. Claim 4 has been cancelled without prejudice and the limitations of cancelled claim 4 are incorporated into claim 1. No new matter has been added. Reference to the "first" and "second" polymers in the claims has been made for purposes of clarifying the components of the tooth adhering layer. These components have already been searched and examined by the Examiner.

B. SUMMARY OF THE CLAIMED INVENTION

The present invention is an erosion-controllable and bioerodible patch for tooth whitening which includes a tooth-adhering layer and an erosion rate-controlling layer. As now defined by the claims amended herein, the tooth adhering layer includes two principal components, namely, an erodible polymer complex and a tooth whitening agent. The erodible complexes in the tooth adhering layer claimed herein require 1-10% by weight of a first polymer containing a carboxyl group and 40-80% by weight of a second polymer containing a carbonyl or ether group. The second component in the claimed bioerodible patch is an erosion rate-controlling layer which includes a mixture of a hydrophilic polymer and a film-forming polymer.

Hydrogen bonding of the first and second polymers in the erodible complexes of the tooth adhering layer allows the patch to firmly adhere to teeth. The whitening agent is released while the patch gradually erodes. The erosion rate and the residence time of the tooth whitening patches can be controlled by varying (i) the composition of the erosion rate-controlling layer and/or (ii) the composition of the erodible complexes in the adhesion layer. Accordingly, the claimed invention allows the release of the tooth whitening agent in a time-controlled manner

and eliminates the need to remove tooth patches from the mouth after the release of the tooth whitening agent is complete.

C. THE CLAIMS ARE NOT RENDERED OBVIOUS BY THE KIM IN VIEW OF MORO

1. Kim et al. Does Not Disclose Erodible Complexes in the Adhesion Layer and the Erosion Rate-Controlling Layer

The Examiner has maintained the rejection of the prior Office Action of March 23, 2006. The subject matter of all pending claims is rejected under 35 USC 103(a) as allegedly obvious over Kim et al. (WO 01/68045 A1) in view of Moro et al. (U.S. Patent No. 6,585,997).

The Examiner has alleged that it would have been obvious to have provided a backing layer on the tooth whitening patches of Kim et al. which was erosion rate-controlling and bioerodible. The Examiner further opines that one could adjust the type and relative proportions of hydrophilic and hydrophobic polymers used therein, motivated by the desire to provide optimal, tailored delivery of the tooth whitening agent by controlling residence time as taught by Moro et al.

Applicant respectfully submits that the Examiner has failed to make a prima facie case of obviousness. The Examiner provides no specifics concerning how the claimed device would be made. Such speculation merely invites one to experiment or provides an invitation to try various steps with hope that one would serendipitously stumble upon the claimed invention. US patent laws are clear that in order to sustain a proper rejection under 35 USC 103(a), the prior art must tell how the claimed invention is rendered obvious. It is respectfully submitted that this burden has not been met.

The dry tooth whitening patches of Kim et al. include a tooth adhesion layer and a backing layer. Kim et al. discloses neither the erosion rate-controlling layer nor the erodible complexes. Furthermore, there is no disclosure to make the adhering layer in a manner so that the claimed amounts of the first and second polymers are present. Instead, Kim et al. is silent regarding the use or inclusion of both polymers, namely, the first polymer containing carboxyl groups and the second polymer containing carbonyl or ether groups. The ineluctable conclusion that must be drawn from this is that it is impossible to infer or let alone describe the claimed adhesion layers which include complexes of both polymers. Moreover, it is speculation that one

would include the erosion rate controlling layer proposed by the Examiner. Even if the Examiner's position were to be believed, a patch containing such a layer on the device of Kim et al. is not the claimed invention.

Furthermore, in support of Applicant's position, Applicant wishes to direct the Examiner's attention to the experimental data in the disclosure. For example, Comparative Example 2 in Table 2 includes an adhesion layer only containing polyvinylpyrrolidone as a carbonyl or ether-containing polymer, and an erosion rate-controlling layer. The adhesion layer of Comparative Example 2 is thus similar to that of Kim et al. not including the erodible complexes in the adhering layer. Unlike other examples including both the carboxyl-containing polymer and the carbonyl or ether-containing polymer and thereby forming the copolymer complexes, Comparative Example 2 was prematurely detached from teeth within less than 30 minutes from the time of application before the patch sufficiently releases a whitening agent. See Table 3. The result shows that the erodible complexes allow the tooth whitening patches to firmly attach to teeth as well as control solubilization of the tooth adhering layer.

Accordingly, those skilled in the art will not be motivated to replace the backing layer of Kim et al. with the erosion rate-controllable layer so that the resulting patch like Comparative Example 2 would be detached from teeth too early. In fact, the backing layer of Kim et al. contains water-insoluble and water-impermeable polymers so that the backing layer prevents the patch of Kim et al. from being detached from teeth by saliva. See page 9, lines 20-25 of Kim et al. Table 3 of the present application shows that the patch of Control 1 corresponding to that of Kim et al stayed on teeth more than 2 hours and thus required removal of the backing layer left behind.

Finding the Applicant's argument in response to the earlier Office Action to be unpersuasive, the Examiner has alleged that "Complex formation would be inherent and indeed expected from the corollary disclosure at page 15, lines 30-34" of Kim et al.

Applicant respectfully disagrees.

Applicant believes that the Examiner's alleged expectation of complex formation is directed to a complex formation between a polymer such as polyvinylpyrrolidone and peroxide, rather than the claimed invention's erodible complex formation between the first carboxyl-containing polymer and the second carbonyl or ether-containing polymer. Kim et al. does not

disclose or suggest the erodible complexes of the carboxyl-containing polymer and the carbonyl or ether-containing polymer explicitly or implicitly.

Accordingly, the present invention as defined by the amendment is distinguished over Kim et al. primarily because of the erosion rate-controlling layer, and the erodible complexes of the carboxyl group-containing polymer and the carbonyl or ether-containing polymer.

2. Moro et al. Does Not Suggest or Teach Modifying The Tooth Whitening Patches of Kim et al. To Contain The Erosion Rate-Controlling Layer

Moro et al. relates to mucosal patches having an adhesive layer and an erodible backing layer. As stated in the argument of the earlier response, since the mucosal patches adhere in a fundamentally different way than the tooth whitening patches, Moro et al. does not suggest or teach modifying the tooth whitening patches of Kim et al. to contain the erodible backing layer or cure the deficiency of Kim et al. regarding the tooth adhering layer.

The Examiner found the argument to be unpersuasive alleging that the bioerodible transmucosal patches of Moro et al. are known to deliver drugs when adhered to teeth as well as mucosal tissues. In support of the Examiner's position, the Examiner provided USP 5,800,832 and USP 4,713,243 to show full scope of the state of the art.

The '832 patent relates to transmucosal patches. Applicant could not find any hints in '831 patent showing that the transmucosal patches capable of adhering to teeth and delivering drugs was known in the art. The '243 patent also relates to transmucosal patches. The transmucosal patches are different from the erosion-rate controlling layer of the present invention. Applicant could not find any hints that the '243 patent indicates that an erosion-rate controlling layer including both a hydrophilic polymer such as hydroxypropyl cellulose and a film-forming polymer such a (meth)acrylic acid copolymer was known to deliver drugs when attached to teeth. The references do not show any hints supporting the Examiner's position.

Accordingly, Moro et al. does not suggest or motivate those in the art to modify the tooth patches of Kim et al. to contain the erodible backing layer. Even if one combined the references, it would still not disclose or suggest the invention as now defined by the claims.

3. The Claimed Invention Is Distinguishable Over The Tooth Whitening Patches of Kim et al Adapted As Taught By Moro et al

Contrary to what the Examiner has contended, those skilled in the art will not be motivated to replace the backing layer of Kim et al. with an erosion rate-controlling layer of Moro et al. Even if those skilled in the art modify the tooth whitening patches of Kim et al. as taught by Moro et al., it does not make the invention as defined by the claims obvious. The tooth whitening patches of Kim et al. adapted as taught by Moro et al. do not contain the erodible complexes of the carboxyl group-containing polymer such as (meth)acrylic acid copolymer in an amount of 1 to 10% of the total dry weight of the adhesion layer, and the carbonyl or ether-containing polymer such as polyvinylpyrrolidone in an amount of 40 to 80% of the total dry weight of the adhesion layer.

As stated above, Comparative Example 2 containing an adhesion layer similar to that of Kim et al. and an erosion rate-controlling layer of the present invention was prematurely detached from teeth within less than 30 minutes from application before full release of a tooth whitening agent. The experimental data shows that the present invention is non-obvious and distinguishable over the modified patch of Kim et al.

Separately, finding the argument of the earlier response, the Examiner has taken the position that “the methods (mechanisms) for controlling release and residence time may or may not be different in each case is not relevant to instant claims, which are limited to products.” Applicant is not, however, arguing or claiming methods. Applicant herein is arguing that the components or compositions claimed herein allow the patches of the present invention to adhere to teeth, and thereafter gradually erode by modifying combinations of the polymer components in the erodible complexes and the erosion rate-controlling layer. See Examples 1-9 in Tables 1 and 3. Table 3 shows various combinations of the polymer components and corresponding residence/adherence time. Both Kim et al. and Moro et al. do not, however, disclose that the erosion rate and adherence time are also controlled by the tooth-adhesion layer not only by the erosion rate-controlling layer.

Accordingly, the claimed invention is not obvious over Kim et al. in view of Moro et al. Reconsideration and removal of the rejection is respectfully requested.

D. FEES

This response is being filed within a shortened period for response. Thus, no further fee is believed to be required. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

E. CONCLUSION

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner have been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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